UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,402	08/01/2003	V. Suzanne Klimberg	781.020US1	6071

21186 7590 01/24/2007

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402

EXAMINER	
MARSCHEL, ARDIN H	
ART UNIT	PAPER NUMBER
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/633,402	KLIMBERG ET AL.	
	Examiner	Art Unit	
	Ardin Marschel	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6,10-14,44-53,55, & 56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6,10-14,44-52,55 and 56* is/are rejected.

7)☒ Claim(s) *53* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *(1 sheet)*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Due to the newly set forth rejections as summarized below, the Finality of the previous office action, mailed 5/15/06, is hereby withdrawn. The amendment, filed 11/14/06, has been entered. Also, due to the above withdrawl of Finality the Notice of Appeal, filed 11/14/06, is deemed moot.

Applicants' arguments, filed 6/14/06, have been fully considered but they are not deemed to be persuasive. Also, said amendment, filed 6/14/06, was timely filed to fully respond to the previous office action, mailed 5/15/06. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

OBVIOUSNESS REJECTION UNDER 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6, 10-14, 44-52, 55, and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Willmore (P/N 5,248,697); taken in view of Good (P/N 6,666,811); taken in view of Pellico (P/N 5,817,695).

Willmore summarizes its disclosure in the abstract wherein glutamine is described as protective against oxidative injury to tissue as a result of treatment and specifically cites radiation-associated oxidative damage in the last three lines therein. Thus, Willmore is directed to glutamine administration for its protective effects as instantly claimed against radiation effects as also reasonably treated as instantly claimed in claims 10-14. Willmore also indicates the radiation therapy therein discussed is directed to cancer patients as cited in column 2, lines 46-57, and more particularly, breast cancer patients as described in column 7, line 66, through column 8, line 9, as instantly claimed. Glutamine administration in dosages within the ranges of instant claims 44-47 are cited in Willmore in column 6, lines 22-34, as well as orally administered as instantly claimed in column 6, lines 22-48. Willmore does not teach the co-administration of carbohydrate to radiation therapy nor the higher dosage of radiation that may be utilized thereby as instantly claimed.

Pellico has been previously cited for teaching the administration of carbohydrate to cancer patients as motivated by the beneficial effects of elemental nutritional products containing carbohydrate as well as other ingredients, as taught, for example, in the abstract. Also, in column 6, line 65, through column 7, line 40, such nutritional product ingredients including carbohydrate is set forth in Pellico. Pellico recognizes therein that cancer patients are treated commonly with accepted treatments via

radiation, chemotherapy, etc. in column 3, lines 21-24. Pellico exemplifies the type of carbohydrate as optionally being dextrose in column 4, line 29, which is a type of carbohydrate as instantly cited in claims 48 and 49. Several examples of Pellico also indicate 100 grams of cornstarch such as in columns 8-12 which when compared to the 0.1 - 2 gm/kg/day(normal 50 kg adult implies 5-100 gm per day) glutamine administration in Willmore at column 6, lines 22-34, gives a ratio of carbohydrate to glutamine of 20:1 to 1:1 which falls within instant claims 50 and 51. The essential invention summary in Pellico in column 6, lines 49-62, suggests the required presence of only 4 amino acids thus suggesting the limited amino acid administration as an option as also required in instant claim 52.

Good at column 54, lines 23-35, suggests that radiation therapy to be effective needs to be much higher by 40-60% than that of normal tissue and thus motivates utilizing high radiation dosages which reasonably are made more doable via any protective effect of radiation to normal tissue as provided by the glutamine administration of Willmore. This also provides a reasonable expectation of success for such increased radiation therapy due to the motivation to do so in Good and the added protective effects of Glutamine administration as described in Willmore. Breast cancer therapy as instantly claimed is recognized in Good as being a radiation treatable cancer in column 59, lines 28-33, as also instantly claimed.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to utilize high radiation dosages permitted by glutamine protection as taught in Willmore and motivated by Good, combined with the additive

effect of a carbohydrate nutritional product as suggested is beneficial for cancer patients via Pellico to result in the practice of the instantly claimed invention.

OBVIOUSNESS-TYPE DOUBLE PATENTING REJECTION

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 6, 10-14, 44-52, 55, and 56 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18-24 of copending Application No. 10/903,500; taken in view of Pellico (P/N 5,817,695); taken further in view of Good (P/N 6,666,811). Although the conflicting claims are not identical, they are not patentably distinct from each other because the monitoring methodology as claimed in 10/903,500 comprises the administration of glutamine to a human breast cancer patient undergoing radiation therapy for its protective effects as

instantly claimed which reasonably lessens such effects as cited in instant claims 10-14. The administration methodology of 10/903,500 is explained via utilizing its specification as a Dictionary for such administration wherein page 4, lines 29-30, of 10/903,500 defines administration to include oral administration as instantly claimed. Copending application 10/903,500 is also used via its specification, in Example 3 on pages 10-12, as a Dictionary regarding defining the amount of glutamine administration to be within the instantly claimed ranges of instant claims 44-47.

Pellico has been previously cited for teaching the administration of carbohydrate to cancer patients as motivated by the beneficial effects of elemental nutritional products containing carbohydrate as well as other ingredients, as taught, for example, in the abstract. Also, in column 6, line 65, through column 7, line 40, such nutritional product ingredients including carbohydrate is set forth in Pellico. Pellico recognizes therein that cancer patients are treated commonly with accepted treatments via radiation, chemotherapy, etc. in column 3, lines 21-24. Pellico exemplifies the type of carbohydrate as optionally being dextrose in column 4, line 29, which is a type of carbohydrate as instantly cited in claims 48 and 49. Several examples of Pellico also indicate 100 grams of cornstarch such as in columns 8-12 which when compared to the 0.5 gm/kg/day(normal 50 kg adult implies 25 gm per day) glutamine administration in 10/903,500 gives a ratio of carbohydrate to glutamine of 4 to 1 which falls within instant claims 50 and 51. The essential invention summary in Pellico in column 6, lines 49-62, suggests the required presence of only 4 amino acids thus suggesting the limited amino acid administration as an option as also required in instant claim 52.

Good at column 54, lines 23-35, suggests that radiation therapy to be effective needs to be much higher by 40-60% than that of normal tissue and thus motivates utilizing high radiation dosages which reasonably are made more doable via any protective effect of radiation to normal tissue as provided by the glutamine administration of 10/903,500. Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to utilize high radiation dosages permitted by glutamine protection as monitored also in 10/903,500 and motivated by Good, combined with the additive effect of a carbohydrate nutritional product as suggested is beneficial for cancer patients via Pellico to result in the practice of the instantly claimed invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

CLAIM OBJECTION

Claim 53 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., AU 1614 Supervisory Patent

Examiner, whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

January 16, 2007

Ardin H. Marschel 1/21/07

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER